

REMARKS

The present application is directed to compositions and methods involving therapeutic delivery compounds. The compounds are particularly suited for the effective delivery of genetic matter and other compounds to the interior of cells. Following entry of this amendment Claims 1, 22-23, 25, 27-33, 35-42 will be pending. Claims 1, 22, 23, 25, 32, 35, 36, 38 and 41 are amended, and Claims 2-21, 24, 26 and 34 are cancelled without prejudice. Claim 37 has been allowed and, as previously indicated by the Examiner, Claims 22-23, 25, 27-33 and 35-42 are free of the prior art of record. No new matter is added and support for the amendments is found throughout the specification.

Claim rejections under 35 U.S.C. § 112, second paragraph

In the March 22, 2005 Office Action, the Examiner rejected Claim 32 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully submit that the amendments to the claim overcome the rejection.

Claim 32 has been amended to specify that the polyoxyethylene portion of the block copolymer is approximately 1% to approximately 50% of the total weight of the block copolymer. Applicants submit that the amended claim clearly defines the block copolymer. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claim rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 1, 6, 7, 9, 14, 15, 18, 19, 21-25 27-36 and 38-42 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement.

The Examiner stated that Claims 1, 6, 7, 9, 14, 15, 18, 19, 21-25 and 27-31 recite the limitation “the polyoxyethylene portion of the block copolymer is approximately 1% to approximately 45% of the total weight of the block copolymer.” The Examiner concluded that there is no support for this limitation. Applicants respectfully traverse.

Block copolymers comprising a polyoxyethylene portion of approximately 1% to approximately 45% of the total weight of the block copolymer are disclosed on at least Table II

(page 17) of the instant application. Table II discloses propriety copolymers that represent both the lower (CRL-8950 (~5%); CRL-1235 (~5%); CRL-1190 (~5%) CRL 336 (~5%)) and upper range (CRL-85174 (~40%)) of the polyoxyethylene portion of the block copolymer as claimed. In addition, applicants direct the Examiner to page 15, lines 30-34, of the present application where applicants state, "It should be understood that the molecular weight and percentage ranges that are described for the block copolymer are to be considered outside ranges and that any population of molecules that falls within the stated ranges is considered an embodiment of the present invention." (emphasis added).

In an effort to facilitate prosecution, applicants have amended the claims to recite that the polyoxyethylene portion of the block copolymer is approximately 1% to approximately 50% of the total weight of the block copolymer. Applicants respectfully submit that, for at least the above reasons, they have overcome the Examiner's rejection under §112, first paragraph, and request its withdrawal.

The Examiner also rejected Claims 32 and 33 for failing to comply with the written description requirement. The Examiner concluded that no copolymers of 750-1000 Daltons were provided. Applicants respectfully traverse.

Copolymer CRL-1187 (having a weight of approximately 750 Da) can be found in Table 2 (page 17 of the instant specification). Moreover, the term "approximately" is defined within the specification to mean the stated concentration plus or minus ten percent (see page 13, lines 21-23 of the present specification). Accordingly, applicants request withdrawal of the Examiner's rejection of Claims 32 and 33 under §112, first paragraph.

The Examiner also rejected Claim 33 for failing to comply with the written description requirement on the basis that a block copolymer having a polyoxyethylene portion of "approximately 10%-30% of the total weight of the block copolymer" was not supported by written description. Applicants respectfully traverse.

Copolymers having a polyoxyethylene portion of approximately 10%-30% of the total weight of the block copolymer can be found in Table 2 (on page 17 of the present specification) and include copolymers such as CRL-1183 (~10%), CRL-1122 (~12%), CRL-9352 (~15%), CRL-1187 (~25%), CRL-8143 (~30%). In addition, the term "approximately" is defined within

the specification to mean the stated concentration plus or minus ten percent (see page 13, lines 21-23 of the present specification). Accordingly, applicants request withdrawal of the Examiner's rejection under §112, first paragraph.

The Examiner rejected Claims 34-36 for failing to comply with the written description requirement on the basis that a block copolymer having a polyoxypropylene portion "between approximately 4400 and 15,000 Daltons" was not supported by written description. Applicants respectfully traverse.

Copolymers having a polyoxypropylene portion of approximately 4400 and 15,000 Daltons, such as copolymers **CRL-8941 (~4400)**, CRL-3632 (~4740), CRL-1122 (~5900), CRL-1235 (~7500), CRL-1190 (~10000), **CRL-336 (~14,000)** can be found in Table 2 (page 17 of the present specification). Moreover, the term "approximately" is defined within the specification to mean the stated concentration plus or minus ten percent (see page 13, lines 21-23 of the present specification). However, in an effort to facilitate prosecution, applicants have amended the claims herein to recite that "the polyoxypropylene portion of approximately **4400** and **14,000** Daltons." Accordingly, applicants request withdrawal of the Examiner's rejection under §112, first paragraph.

The Examiner also rejected Claims 41 and 42 for failing to comply with the written description requirement on the basis that a block copolymer having a polyoxypropylene portion "between approximately 4740 and 15,000 Daltons" was not supported by written description. Applicants respectfully traverse.

Copolymers having a polyoxypropylene portion of approximately 4740 and 15,000 Daltons, such as copolymers **CRL-3632 (~4740)**, CRL-1122 (~5900), CRL-1235 (~7500), CRL-1190 (~10000), **CRL-336 (~14,000)** can be found in Table 2 (page 17 of the present specification). Moreover, the term "approximately" is defined within the specification to mean the stated concentration plus or minus ten percent (see page 13, lines 21-23 of the present specification). However, in an effort to facilitate prosecution, applicants have amended the claims herein to recite that "the polyoxypropylene portion of approximately **4740** and **14,000** Daltons." Accordingly, applicants request withdrawal of the Examiner's rejection under §112, first paragraph.

Claim rejections under 35 U.S.C. § 102

In the Office Action mailed March 22, 2005, the Examiner rejected Claims 1-4, 9-12, and 19 as anticipated by Allison *et al.*, U.S. 5,376,369 (hereinafter “Allison *et al.*”) under 35 U.S.C. §102(b). The Examiner stated that Allison *et al.* teach that Pluronics L101, L121 and L122 could be used as adjuvants in the delivery of whole viruses *in vivo* as vaccines and that an expression vector capable of expressing the genes is anticipated by the viruses themselves, which are capable of expressing their own genes.

Applicants respectfully submit that Claim 1 has been amended to include the limitations of Claim 18, now cancelled, which the Examiner indicated was free of the prior art. Claims 2-4, 9-12 and 19 have also been cancelled. Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b).

The Examiner rejected Claims 1-3, 9-11, 19 and 21 as being anticipated under 35 U.S.C. § 102(e) by Wasmoen *et al.*, U.S. 5,656,275 (hereinafter “Wasmoen *et al.*”) as evidenced by Osorio *et al.*, WO 99/39733 (hereinafter “Osorio *et al.*”). The Examiner stated that Wasmoen *et al.* teach that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses *in vivo* as vaccines and that an expression vector capable of expressing genes is anticipated by viruses, which are capable of expressing their own genes.

Applicants respectfully submit that Claim 1 has been amended to include the limitations of Claim 18, now cancelled, which the Examiner indicated was free of the prior art. Claims 2-3, 9-11, 19 and 21 have also been cancelled. Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(e).

Claim rejections under 35 U.S.C. § 103

In the March 22, 2005 Office Action, the Examiner rejected Claims 1, 6, 7, 9, 14-15 and 34 as being unpatentable under 35 U.S.C. § 103(a) over Wasmoen *et al.* in view of Miyamura *et al.* U.S. 5,372,928 (hereinafter “Miyamura *et al.*”). The Examiner stated that Wasmoen *et al.* teach that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses *in vivo* as vaccines and that whole viruses could be considered expression vectors.

Applicants respectfully submit that Claim 1 has been amended to include the limitations of Claim 18, now cancelled, which the Examiner indicated was free of the prior art. Claims 6, 7, 9, 14-15 and 34 have also been cancelled. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims under 35 U.S.C. §103(a).

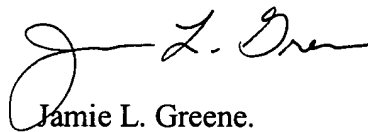
CONCLUSION

The foregoing is submitted as a full and complete Response to the Final Office Action mailed on March 22, 2005. For at least the reasons given above, applicants respectfully submit that the pending claims are definite, novel and non-obvious. Accordingly, applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

The Examiner is invited and encouraged to contact the undersigned attorney of record at 404-745-2473 or the telephone number listed below, if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,



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